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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/809,312	03/24/2004	Lloyd A. Greene	5199-69	6486

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EXAMINER	
MCGILLEM, LAURA L	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 08/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/809,312	GREENE ET AL.	
	Examiner	Art Unit	
	Laura McGillem	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *3/24/2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-31* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-20, drawn to a population of differentiated neural cells, a method of isolating a population of differentiated cells, a method of promoting differentiation of neural stem cells by inhibiting ATF5 and contacting the cell with a neurotrophic factor and a method of treating nervous tissue degeneration by promoting differentiation of neural stem cells and transplanting the differentiated neural cell into the subject, classified in class 424, subclass 93.21, for example.

II. Claim 21, drawn to a method for identifying an agent for use in treating a condition, classified in class 435, subclass 4, for example.

III. Claim 22, drawn to a method for suppressing differentiation of neural stem cells by adding ATF5, classified in class 435, subclass 4, for example.

IV. Claims 23, 27 and 31, drawn to an ATF5 inhibiting agent, a kit comprising an ATF5 specific agent, and a therapeutic composition, classified in class 435, subclass 320.1, for example.

V. Claims 24-26, drawn to a method for identifying an agent which inhibits ATF5, classified in class 435, subclass 4, for example.

VI. Claim 28, drawn to a method to determine whether a subject has a neural tumor by assaying a diagnostic sample for ATF5, classified in class 435, subclass 4, for example.

VII. Claims 29 and 30, drawn to a method for assessing the efficacy of a therapy to treat a neural tumor comprising assaying a sample for ATF5 levels and a method for assessing the prognosis of a subject by assaying a sample for ATF5 levels, classified in class 435, subclass 4, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions IV and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product can be used in a materially different process of use for that product such as for identification of an agent for use in treating a condition associated with nervous tissue degeneration.

Inventions IV and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product can be used in a materially different process of use for that product such as for identifying an agent which inhibits ATF5.

Inventions IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product can be used in a materially different process of use for that product such as for determining whether a subject has a neural tumor.

Inventions IV and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product can be used in a materially different process of use for that product such as for assessing the efficacy of a therapy to treat a neural tumor.

Inventions I-III and V-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are patentably distinct because they are comprised of different steps and have distinct outcomes. The invention of Group I is a method of treating nervous tissue degeneration by promoting differentiation

of neural stem cells and transplanting the differentiated neural cell into a subject, which has distinct steps from the method of Group II, a method for identifying an agent for use in treating a condition; Group III, a method for suppressing differentiation of neural stem cells by adding ATF5; Group V, a method for identifying an agent which inhibits ATF5; Group VI, a method to determine whether a subject has a neural tumor by assaying a diagnostic sample for ATF5; and Group VII, a method for assessing the efficacy of a therapy to treat a neural tumor comprising assaying a sample for ATF5 levels. The outcome of the method of Group I is treatment of a subject with nervous tissue degeneration, while the outcome of Group II is an identified agent for treating conditions, the outcome of Group III is suppression of differentiation, the outcome of Group V is an identified agent to inhibit ATF5, the outcome of Group V is the diagnosis of a neural tumor and the outcome of Group VI is assessment of treatment of a subject.

The invention of Group II is a method for identifying an agent for use in treating a condition which has distinct steps from Group I, a method of treating nervous tissue degeneration by promoting differentiation of neural stem cells; Group III, a method for suppressing differentiation of neural stem cells; Group V, a method for identifying an agent which inhibits ATF5; Group VI, a method to determine whether a subject has a neural tumor; and Group VII, a method for assessing the efficacy of a therapy to treat a neural tumor. The outcome of the method of Group II is an identified agent for treating a condition, while the outcome of Group I is treatment of a subject with a degenerative disease, the outcome of Group III is suppression of differentiation, the outcome of Group V is an identified agent that inhibits ATF5, the outcome of Group VI is the

diagnosis of a neural tumor and the outcome of Group VII is assessment of treatment of a subject.

The invention of Group III is a method for suppressing differentiation of neural stem cells, which has distinct steps from Group I, a method of treating nervous tissue degeneration by promoting differentiation of neural stem cells; Group II, a method for identifying an agent for use in treating a condition; Group V, a method for identifying an agent which inhibits ATF5; Group VI, a method to determine whether a subject has a neural tumor; and Group VII, a method for assessing the efficacy of a therapy to treat a neural tumor. The outcome of the method of Group III is suppression of differentiation, while the outcome of Group I is treatment of a subject with nervous tissue degeneration; the outcome of Group II is an identified agent for treating a condition, the outcome of Group V is an identified agent that inhibits ATF5, the outcome of Group VI is the diagnosis of a neural tumor and the outcome of Group VII is assessment of treatment of a subject.

The invention of Group V is a method for identifying an agent which inhibits ATF5, which has distinct steps from Group I, a method of treating nervous tissue degeneration by promoting differentiation of neural stem cells; Group II, a method for identifying an agent for use in treating a condition; Group III, a method for suppressing differentiation of neural stem cells by adding ATF5; Group VI, a method to determine whether a subject has a neural tumor; and Group VII, a method for assessing the efficacy of a therapy to treat a neural tumor comprising assaying a sample for ATF5 levels. The outcome of Group V is an identified agent that inhibits ATF5, while the

outcome of Group I is treatment of a subject with nervous tissue degeneration, the outcome of Group II is an identified agent for treating conditions, the outcome of Group III is suppression of differentiation, the outcome of Group VI is the diagnosis of a neural tumor and the outcome of Group VII is assessment of treatment of a subject.

The invention of Group VI is a method to determine whether a subject has a neural tumor by assaying a diagnostic sample for ATF5, which has distinct steps from Group I, a method of treating nervous tissue degeneration by promoting differentiation of neural stem cells; Group II, a method for identifying an agent for use in treating a condition; Group III, a method for suppressing differentiation of neural stem cells by adding ATF5; Group V, a method for identifying an agent which inhibits ATF5; and Group VII, a method for assessing the efficacy of a therapy to treat a neural tumor comprising assaying a sample for ATF5 levels. The outcome of the method of Group VI is the diagnosis of a neural tumor, while the outcome of Group I is treatment of a subject with nervous tissue degeneration, the outcome of Group II is an identified agent for treating conditions, the outcome of Group III is suppression of differentiation, the outcome of Group V is an identified agent that inhibits ATF5, and the outcome of Group VII is assessment of treatment of a subject.

The invention of Group VII is a method for assessing the efficacy of a therapy to treat a neural tumor comprising assaying a sample for ATF5 levels, which has distinct steps from Group I, a method of treating nervous tissue degeneration by promoting differentiation of neural stem cells; Group II, a method for identifying an agent for use in treating a condition; Group III, a method for suppressing differentiation of neural stem

cells by adding ATF5; Group V, a method for identifying an agent which inhibits ATF5; and Group VI, a method to determine whether a subject has a neural tumor by assaying a diagnostic sample for ATF5. The outcome of the method of Group VII is assessment of treatment of a subject while the outcome of Group I is treatment of a subject with nervous tissue degeneration, the outcome of Group II is an identified agent for treating conditions, the outcome of Group III is suppression of differentiation, the outcome of Group V is an identified agent to inhibit ATF5, and the outcome of Group VI is the diagnosis of a neural tumor.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is

found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura McGillem whose telephone number is (571) 272-8783. The examiner can normally be reached on M-F 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Laura McGillem, PhD
8/12/2005

DAVID GUZO
PRIMARY EXAMINER